EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to partially hydrolysed guar gum (PHGG) and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 788), changes in short chain fatty acid (SCFA) production and/or pH in the gastrointestinal tract (ID 787, 813), changes in bowel function (ID 813, 853, 1902, 1903, 1904, 2929, 2930, 2931), and reduction of gastro-intestinal discomfort (ID 813, 1902, 1903, 1904, 2929, 2930, 2931) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to partially hydrolysed guar gum (PHGG) and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 788), changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 787, 813), changes in bowel function (ID 813, 853, 1902, 1903, 1904, 2929, 2930, 2931), and reduction of gastro-intestinal discomfort (ID 813, 1902, 1903, 1904, 2929, 2930, 2931) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to partially hydrolysed guar gum and decreasing potentially pathogenic gastro-intestinal microorganisms, changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract, changes in bowel function, and reduction of gastro-intestinal discomfort. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is partially hydrolysed guar gum (PHGG). The Panel considers that partially hydrolysed guar gum is sufficiently characterised.

[1] On request from the European Commission, Question No EFSA-Q-2008-1574, EFSA-Q-2008-1575, EFSA-Q-2008-1600, EFSA-Q-2008-1640, EFSA-Q-2008-2635, EFSA-Q-2008-2636, EFSA-Q-2008-2637, EFSA-Q-2008-3661, EFSA-Q-2008-3662, EFSA-Q-2008-3663, adopted on 25 March 2011.

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[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren.

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Decreasing potentially pathogenic gastro-intestinal microorganisms

The claimed effect is "bowel health/prebiotic effect". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increasing numbers of bacteria that are considered to be "beneficial". The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect *per se*. The Panel considers that the claimed effect, in the context of decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.

No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and decreasing potentially pathogenic gastro-intestinal microorganisms.

Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract

The claimed effects are "bowel health/SCFA production" and "improved intestinal conditions (pH, SCFA production) and intestinal function". The target population is assumed to be the general population. The Panel notes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract. The Panel considers that changes in SCFA production and pH in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. No information has been provided about the context in which the claimed effect could be considered as a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

Changes in bowel function

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", "bowel function", and "intestinal health and regularity". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to changes in bowel function. The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.

In weighing the evidence, the Panel took into account that the only human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show any effect of PHGG on stool frequency or consistency, and that PHGG induced an increase rather than a decrease in colonic transit time.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and changes in bowel function.

Reduction of gastro-intestinal discomfort

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal function", and "intestinal health and regularity". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of gastro-intestinal discomfort. The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and reduction of gastro-intestinal discomfort.

KEY WORDS

Partially hydrolysed guar gum, potentially pathogenic gastro-intestinal microorganisms, bowel function, gastro-intestinal discomfort, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is partially hydrolysed guar gum (PHGG).

PHGG is produced from guar gum by digestion with D-mannanase. It has a low viscosity and a molecular weight of about 20 kDa. PHGG is not naturally occurring in foods, and is usually consumed in the form of food supplements. PHGG can be measured in foods by established methods.

The Panel considers that the food constituent, partially hydrolysed guar gum, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 788)

The claimed effect is "bowel health/prebiotic effect". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increasing numbers of bacteria that are considered to be "beneficial".

The numbers/proportions of bacterial groups that would constitute a "beneficial/healthy/good/or natural balance" of gastro-intestinal flora have not been established. Increasing the number of any group of microorganisms, including lactobacilli and/or bifidobacteria, is not in itself considered to be a beneficial physiological effect.

The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect.

The Panel considers that the claimed effect, in the context of decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.

2.2. Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 787, 813)

The claimed effects are "bowel health/SCFA production" and "improved intestinal conditions (pH, SCFA production) and intestinal function". The Panel assumes that the target population is the general population.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

The Panel notes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract. The Panel considers that changes in SCFA production and pH in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. No information has been provided about the context in which the claimed effect could be considered as a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

2.3. Changes in bowel function (ID 813, 853, 1902, 1903, 1904, 2929, 2930, 2931)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", "bowel function", and "intestinal health and regularity". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to changes in bowel function.

The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.

2.4. Reduction of gastro-intestinal discomfort (ID 813, 1902, 1903, 1904, 2929, 2930, 2931)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal function" and "intestinal health and regularity". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the reduction of gastro-intestinal discomfort.

The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 788)

Among the references provided were narrative reviews which did not provide original data for the scientific substantiation of the claim, one human intervention study on the combination of fructo-oligosaccharides and PHGG which provided no information about the effects of PHGG alone, and human intervention studies which addressed the effects of PHGG on health outcomes (e.g. SCFA concentration in faeces, cholecystokinin concentration in blood, colonic fluid secretion, intestinal transit, constipation, and incidence of diarrhoea in patients receiving total parenteral nutrition) other than the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

In an open label, one-arm, uncontrolled human intervention study, Okubo et al. (1994) evaluated the effect of 7 g of PHGG given three times daily on intestinal microflora. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of PHGG consumption on potentially pathogenic gastro-intestinal microorganisms *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and decreasing potentially pathogenic gastro-intestinal microorganisms.

3.2. Changes in bowel function (ID 813, 853, 1902, 1903, 1904, 2929, 2930, 2931)

Among the references provided for the scientific substantiation of the claim were textbooks and narrative reviews which did not contain any original data for the scientific substantiation of the claim. Some human studies were not related to the food constituent which is the subject of the claim, examined the effect of PHGG in combination with other substances, or addressed health outcomes (e.g. prevention and treatment of diarrhoea) other than the claimed effect. One reference was not accessible to the Panel after every reasonable effort to retrieve it had been made. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Five human intervention studies addressed the effects of PHGG on intestinal transit time/frequency of defecations.

Four of the human studies provided were one-arm, uncontrolled, open label studies which evaluated the effects of PHGG supplementation on different measures of bowel function (Giaccari et al., 2001; Patrick et al., 1998; Takahashi et al., 1993; Takahashi et al., 1994). The Panel notes that these studies were uncontrolled, and considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

A randomised, controlled, cross-over study by Meier et al. (1993) reported on the effects of a standardised diet and two liquid formula diets, with and without supplementation of PHGG (21 g/L), on oro-caecal and colonic transit time in 12 healthy male volunteers. The diets were consumed in a randomised order for seven days each. PHGG did not significantly affect oro-caecal transit time. Colonic transit time, however, was significantly prolonged (55 hours) with the liquid diet containing PHGG compared to the liquid diet without PHGG (39 hours), and to the normal diet (30 hours) ($p<0.01$). Stool frequency and consistency were not significantly affected by PHGG supplementation. The Panel notes that this study does not show a significant effect of PHGG on stool frequency or consistency, and that PHGG increased rather than decreased colonic transit time.

In weighing the evidence, the Panel took into account that the only human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show any effect of PHGG on stool frequency or consistency, and that PHGG induced an increase rather than a decrease in colonic transit time.

The Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and changes in bowel function.

3.3. Reduction of gastro-intestinal discomfort (ID 813, 1902, 1903, 1904, 2929, 2930, 2931)

A number of the references provided in relation to the claim were textbooks and narrative reviews which did not provide any original data for the scientific substantiation of the claim. Some human studies were not related to the food constituent which is the subject of the claim, examined the effect of PHGG in combination with other substances, or addressed outcomes (e.g. measures of bowel function, and prevention and treatment of diarrhoea) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Four human intervention studies which addressed gastro-intestinal discomfort, were provided.

One of the human studies was a one-arm, open label, uncontrolled study on the effects of PHGG (5 g/day for 24 weeks) on frequency of defecation and intensity of symptoms in patients with irritable

bowel syndrome (IBS) (Giaccari et al., 2001). The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

In a randomised, not placebo-controlled, open label study, Parisi et al. (2005) assessed the effects of PHGG supplementation on gastro-intestinal symptoms and quality of life in IBS patients, who were randomly assigned to consume 60 mL of an apple-flavoured beverage providing either 10 g/day (n=40) or 5 g/day (n=46) of PHGG for 12 weeks. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

In a multicentre, randomised, open label study, Parisi et al. (2002) investigated the effect of PHGG (5 g/day) compared to wheat bran (30 g/day) on gastro-intestinal symptoms in 188 IBS patients. After four weeks, patients were allowed to voluntarily change intervention, depending on their subjective evaluation of symptoms. The severity of abdominal pain was assessed in a semi-structured interview designed for the purpose of the study, and the overall effect of the intervention was assessed by asking the subjects whether IBS symptoms were worse, unchanged or better compared to baseline. No information on the validity of this method was given. The Panel notes that this study was not blinded, and that no information was given about the validity of the methods used for assessing the effect of the intervention. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a parallel study in 40 patients with constipation predominant IBS (28 females, mean age 54 years), Uneddu et al. (2005) assessed the effect of consuming 10 g/day of PHGG compared to 100 g of bread (made of 70 % hard wheat flour, bran and refined bran, consisting in a total of 10.4 g of fibre on average) for 60 days. The frequency and intensity of abdominal symptoms were assessed by a 4-point Likert scale questionnaire. No information about the validity of the questionnaire used was given. The Panel notes that the intervention was not blinded, and that successful blinding of subjects is particularly important when evaluating self-reported health outcomes for which a high placebo effect can be expected. The Panel considers that no conclusions can be drawn from this unblinded study, which used a non-validated questionnaire for abdominal symptom assessment, for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of partially hydrolysed guar gum consumption on a decrease in potentially pathogenic gastro-intestinal microorganisms *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and reduction of gastro-intestinal discomfort.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, partially hydrolysed guar gum, which is the subject of the health claims, is sufficiently characterised.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 788)

- The claimed effect is "bowel health/prebiotic effect". The target population is assumed to be the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and decreasing potentially pathogenic gastro-intestinal microorganisms.

Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 787, 813)

- The claimed effects are "bowel health/SCFA production" and "improved intestinal conditions (pH, SCFA production) and intestinal function". The target population is assumed to be the general population. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

Changes in bowel function (ID 813, 853, 1902, 1903, 1904, 2929, 2930, 2931)

- The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", "bowel function", and "intestinal health and regularity". The target population is assumed to be the general population. Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.
- A cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and changes in bowel function.

Reduction of gastro-intestinal discomfort (ID 813, 1902, 1903, 1904, 2929, 2930, 2931)

- The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal function", and "intestinal health and regularity". The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the reduction of gastro-intestinal discomfort. Reduction of gastro-intestinal discomfort is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of partially hydrolysed guar gum and reduction of gastro-intestinal discomfort.

Documentation provided to EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1574, EFSA-Q-2008-1575, EFSA-Q-2008-1600, EFSA-Q-2008-1640, EFSA-Q-2008-2635, EFSA-Q-2008-2636, EFSA-Q-2008-2637, EFSA-Q-2008-3661, EFSA-Q-2008-3662, EFSA-Q-2008-3663). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or
b) psychological and behavioural functions; or
c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and
(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to partially hydrolysed guar gum (PHGG), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
787	Partially Hydrolysed Guar Gum (PHGG)	Bowel health/SCFA production	PHGG is fermented in the gut leading to the production of the beneficial SCFA. PHGG helps promote colon health PHGG nourishes the digestive tract, where 70% of immune function occurs.
	Conditions of use - AI for total fiber (IOM): 26-38 g/day (ideally 8.5-12.5 g/day soluble fiber) - Sonden- und Trinknahrungen		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
788	Partially Hydrolysed Guar Gum (PHGG)	Bowel health/prebiotic effect	PHGG promotes the growth of beneficial intestinal bacteria (probiotics) that are important for the maintenance of the natural digestive balance PHGG supports the natural, beneficial microflora PHGG contributes to proper digestive function by regulating the microflora and short chain fatty acid production. PHGG helps promote healthy intestinal flora to support bowel function PHGG helps maintain digestive balance by promoting "good bacteria" levels PHGG helps to restore and maintain your natural digestive balance by stimulating the growth of beneficial intestinal flora PHGG acts as a prebiotic to naturally nourish the beneficial bacteria found in your digestive system PHGG stimulates the development of the intestinal flora PHGG helps to maintain the natural balance of the intestinal flora PHGG has a prebiotic effect Thanks to the prebiotic activity of PHGG, the product has a gentle, effective and progressive action: it

			helps good development of the intestinal flora
	Conditions of use - Sonden- und Trinknahrungen - 3- 22 g/day. Must meet minimum requirements for use of the claim "Source of fibre" as per Annex to Regulation 1924/2006. - AI for total fiber (IOM): 26-38 g/day. (ideally 8.5-12.5 g/day soluble fiber). PHGG: 3-11 g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
813	Guar gum partially hydrolyzed	Improved intestinal conditions (pH, SCFA production) and intestinal function	Promotes good intestinal health. Improves bowel function and gut comfort.
	Conditions of use - Must meet minimum requirements for use of the claim "Source of fibre" as per Annex to Regulation 1924/2006. - AI for total fiber (IOM): 26-38 g/day (ideally 8.5-12.5 g/day soluble fiber) PHGG general: 5–10 g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
853	Hydrolised guar gum	Bowel function	Improves health bowel/helps promote regularity
	Conditions of use - 5 g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1902	Sunfiber (enzymatically partially depolymerised guar gum).	Intestinal health and regularity. In healthy people:	Improves intestinal regularity. Improves bowel function and gut comfort.
	Conditions of use - 8 – 12 g/d or more		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1903	Sunfiber (enzymatically partially depolymerised guar gum).	Intestinal health and regularity. In people with irritable bowel syndrom:	Improves intestinal comfort in people with irritable bowel syndrom
	Conditions of use - 5 – 10 g/d or more		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1904	Sunfiber (enzymatically partially depolymerised guar gum).	Intestinal health and regularity. In people receiving total or supplemental enteral nutrition	Improves intestinal regularity. Improves bowel function and gut comfort. Promotes a normal intestinal function.
	Conditions of use - 7 – 36 g/day or more		

ID	Food or Food constituent	Health Relationship	Proposed wording
2929	Sunfiber (enzymatically partially depolymerised guar gum)	Intestinal health and regularity In healthy people:	Improves intestinal regularity; Improves bowel function and gut comfort
	Conditions of use - 8 – 12 g/d or more		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2930	Sunfiber (enzymatically partially depolymerised guar gum)	Intestinal health and regularity In people with irritable bowel syndrom:	Improves intestinal comfort in people with irritable bowel syndrom
	Conditions of use - 5 – 10 g/d or more		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2931	Sunfiber (enzymatically partially depolymerised guar gum)	Intestinal health and regularity In people receiving total or supplemental enteral nutrition	Improves intestinal regularity; Improves bowel function and gut comfort ; Promotes a normal intestinal function
	Conditions of use - 7 – 36 g/day or more		

GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
FOS	Fructo-oligosaccharide
IBS	Irritable bowel syndrome
PHGG	Partially hydrolysed guar gum
SCFA	Short chain fatty acid